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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/995,793	11/29/2001	Bernard H. F. Weber	033488-001	9153

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EXAMINER	
LOCKARD, JON MCCLELLAND	

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 08/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/995,793	WEBER ET AL.	
	Examiner	Art Unit	
	Jon M Lockard	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-31 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-31 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-5, 7-8, 10, and 28 (in part), drawn to polynucleotides, vectors, host cells, and methods of recombinantly producing a polypeptide, classified in class 536, subclass 23.5, class 435, subclasses 320.1 and 252.3, for example.

II. Claims 6 and 9, drawn to polypeptides, classified in class 530, subclass 350.

III. Claim 11, drawn to antisense RNA, classified in class 536, subclass 24.5.

IV. Claim 12, drawn to ribozymes, classified in class 536, subclass 24.5.

V. Claim 13, drawn to an inhibitor of a polypeptide, classification dependent upon compound structure.

VI. Claims 14-15 (each in part), 17, and 18-19 (each in part), drawn to methods for diagnosis of macular degeneration or a predisposition for macular degeneration by detecting/measuring a polypeptide, classified in class 435, subclass 7.1, for example.

VII. Claims 14-15 (each in part), 16, and 18-19 (each in part), drawn to methods for diagnosis of macular degeneration or a predisposition for macular degeneration by detecting/measuring a polynucleotide, classified in class 435, subclass 6, for example.

VIII. Claims 20-21 (each in part) and 22, drawn to methods for treating macular degeneration or a predisposition for macular degeneration by administering an

antisense which decreases expression of C7orf9, C12orf7, MPP4, and/or F379, classified in class 514, subclass 44, for example.

IX. Claims 20-21 (each in part), and 23, drawn to methods for treating macular degeneration or a predisposition for macular degeneration by administering a ribozyme which decreases expression of C7orf9, C12orf7, MPP4, and/or F379, classified in class 514, subclass 44.

X. Claims 24-25, drawn to methods for treating macular degeneration or a predisposition for macular degeneration by administering an inhibitor of C7orf9, C12orf7, MPP4, and/or F379 protein, classified in class 514, subclass 1, for example.

XI. Claims 20 (in part) and 26, drawn to methods for treating macular degeneration or a predisposition for macular degeneration by administering a reagent which leads to an increase of a biologically active C7orf9, C12orf7, MPP4, and/or F379 protein, classified in class 514, subclass 44, for example.

XII. Claims 20 (in part) and 27, drawn to methods for treating macular degeneration or a predisposition for macular degeneration by administering C7orf9, C12orf7, MPP4, and/or F379 protein, classified in class 514, subclass 2, for example.

XIII. Claim 28 (in part), drawn to a kit for detecting macular degeneration or a predisposition for macular degeneration comprising a C7orf9, C12orf7, MPP4, and/or F379 antibody, classified in class 435, subclass 7.1.

XIV. Claim 29, drawn to transgenic non-human animals comprising a nucleic acid molecule of Invention I, classified in class 800, subclass 14, for example.

XV. Claims 30-31, drawn to transgenic non-human animals comprising at least one inactivated version of the C7orf9, C12orf7, MPP4, and/or F379 encoding nucleic acid molecule, classified in class 800, subclass 14, for example.

2. The inventions are distinct, each from the other because of the following reasons:

Each of inventions I, II, III, IV, V, XIII, XIV, and XV are unrelated to each other. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the polynucleotides, polypeptides, antisense RNAs, ribozymes, inhibitors of the polypeptide, kits comprising antibodies, and transgenic animals are all physically and functionally distinct chemical entities, or in the case of the transgenic animals, an organism, that have different structures, activities, and functions.

3. Invention I and VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product, or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polynucleotide of Invention I can be used for the method of diagnosis or for the recombinant production of the encoded protein, which are materially different methods.

4. Invention I and each of VI and VIII-XII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04 and 808.01). In the instant case the different Inventions of I and each of VI, VII, IX-XIII, and XV are unrelated product and

methods, wherein each is not required, one for another. For example, the claimed Inventions VI, VII, IX-XIII, and XV do not require the use of polynucleotides of Invention I.

5. Invention II is related to Inventions VI and XII in that the polypeptides are detected/measured or administered in the methods, however, the polypeptides can also be used in a method of generating antibodies, which is a materially different method.

6. Invention II and each of VII-XV are unrelated. In the instant case the different inventions of Inventions II and each of VII-X and XIII-XV are unrelated product and methods, wherein each is not required, one for another. For example, the claimed methods of Inventions VII-XV do not require the use of the polypeptide of Invention II.

7. Invention III is related to Invention VIII in that the antisense RNA is used in the method of treatment which decreases expression of a protein, however, the method can also be practiced with a ribozyme, which is a materially different product.

8. Invention III and each of VI-VII and IX-XII are unrelated. In the instant case the different inventions of Inventions III and each of VI-VII and IX-XII are unrelated product and methods, wherein each is not required, one for another. For example, the claimed methods of Inventions VI-VII and IX-XII do not require the use of the antisense RNA of Invention III.

9. Invention IV is related to Invention IX in that the ribozyme is used in the method of treatment which decreases expression of a protein, however, the method can also be practiced with an antisense RNA, which is a materially different product.

10. Invention IV and each of VI-VIII and X-XII are unrelated. In the instant case the different inventions of Inventions IV and each of VI-VIII and X-XII are unrelated product and

methods, wherein each is not required, one for another. For example, the claimed methods of Inventions VI-VIII and X-XII do not require the use of the ribozymes of Invention IV.

11. Invention V is related to Invention X in that the inhibitor of the polypeptide is used in the method of treatment of Invention X, however, the method can also be practiced with an antibody, which is a materially different product.

12. Invention V and each of VI-IX and XI-XII are unrelated. In the instant case the different inventions of Inventions V and each of VI-IX and XI-XII are unrelated product and methods, wherein each is not required, one for another. For example, the claimed methods of Inventions VI-IX and XI-XII do not require the use of the inhibitor of a polypeptide of Invention V.

13. Invention XIII is related to Invention VI in that the kit of Invention XIII can be used in the method of detecting/measuring a polypeptide of Invention VI, however, the antibody can be used to purify the protein, which is a materially different method.

14. Invention XIII and each of Inventions VII-XII are unrelated. In the instant case the different inventions of Inventions XIII and each of VII-XII are unrelated product and methods, wherein each is not required, one for another. For example, the claimed methods of Inventions VII-XII do not require the use of the kit comprising an antibody of Invention XIII.

15. Although there are no provisions under the section for "Relationship of Inventions" in MPEP § 806.05 for Inventions that are directed to different methods, restriction is deemed to be proper because these methods appear to constitute patentable distinct inventions for the following reasons: Inventions VI-XII are directed to methods that are distinct both physically and functionally, have different method steps, starting compounds, and goals, and are not required one for the other.

16. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, recognized divergent subject matter, and/or separate search requirement, restriction for examination purposes as indicated is proper.

Further Restriction Within Inventions I-XV

17. Which ever Invention is elected, further restriction within the elected Invention is required to one of the following groups:

Inventions directed toward C7orf9, C12orf7, MPP4, or F379

18. Although the classifications for the nucleic acids, proteins, and antibodies are overlapping, each represents a patentably distinct product, having different sequences, encoding different proteins, and requiring separate searches. Furthermore, the antisense RNAs, ribozymes, and methods of using the nucleic acids, antisense RNAs, ribozymes, proteins, inhibitors, and antibodies are also therefore patentably distinct.

19. **Applicants are advised that this is not a species election.**

20. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to

final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

21. In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

22. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

23. A telephone call was made to Teresa Rea on 28 July 2004 to request an oral election to the above restriction requirement, but did not result in an election being made.

24. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

25. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Jon M. Lockard, Ph.D.** whose telephone number is **(571) 272-2717**. The examiner can normally be reached on Monday through Friday, 8:00 AM to 6:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Gary Kunz, Ph.D.** can be reached on **(571) 272-0887**.

The fax number for the organization where this application or proceeding is assigned is **703-872-9306**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see **http://pair-direct.uspto.gov**. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at **866-217-9197** (toll-free).

JML
July 27, 2004

Eileen B. O'Hara

EILEEN B. O'HARA
PATENT EXAMINER